

Rejection under 35 U.S.C. § 112, first paragraph

The Office Action states that in applicant's amendment, filed August 7, 2001, the instant claims 1-8 and 10 were amended to recite the negative limitation that the ligand of this invention Ais not an antibody having the myelomonocytic recruitment inhibitory activity of monoclonal antibody 5C6. The Office Action states that, for support for this amendment, applicants point to page 22, lines 27-28, where it states that ABalb/C mice were given intraperitoneal injections of either CR3 antibodies (1 mg of clone M/170 or 0.5 mg of 5C6), both of which are non-opsonizing antibodies (8,32). The Office Action then states that the record does not set forth a clear nexus between Anon-opsonizing activity as recited in the instant specification, and not having a myelomonocytic recruitment inhibitory activity as now recited in the instant claims. The Office Action concludes that even if there is a nexus, it is not clear from the record that these two activities encompass embodiments of identical scope.

The Office Action further states that applicants also contend that support for the claims as amended can be found in references 8, 11 and 13 as cited on pages 2 and 23-34 of the instant specification, wherein the examiner notes that these references are referred to by number, and also as listed with titles in the reference section on page 27 of the instant specification. The Office Action notes that the applicants further contend that all the references cited in the instant application are incorporated in their entireties by reference as stated on page 25 of the instant specification and are part of the specification as if they were fully set out therein. The examiner then cites Advanced Display Systems, Inc. v. Kent State Univ., 54 USPQ2d 1673 (Fed. Cir. 2000) citing In re de Seversky, 177 USPQ 144, 146 (CCPA 1973) in support of her position that to incorporate material by reference, the host document/application must identify with detailed particularity what specific material it incorporates and clearly indicate where the material is found in the various documents.

The Office Action goes on to allege that her position is further supported by Ex parte Raible, 8 USPQ2d 1709 (BPAI 1988) wherein the appellant's specification did not specifically refer to the Bently reference, and the BPAI agreed with the examiner that the general incorporation by reference in the specification of the application under examination is insufficient to support specific claim limitations. Therefore, according to the examiner, the negative limitation to the instant claims is not supported by the instant application.

The Office Action further states that applicants have urged that Atmel Corp. vs. Information Storage Devices, Inc., 53 USPQ2d 1225 (Fed. Cir. 1999) supports their position that recitation of a reference title in the specification provides a description of matter inserted into the claims. The Office Action then alleges that the fact situation in Atmel does not correspond to the instant application. According to the examiner, in Atmel, the title was discussed in the body of the specification in relationship to the citing of a reference that showed art known features that were taught as being capable of being incorporated by reference into the disclosed invention. The examiner goes on to state that in the instant specification, the title is merely cited in a bibliography, and there was nothing in the body of the disclosure to indicate that applicant was directing one to negate embodiments involving an antibody having the myelomonocytic recruitment activity of the monoclonal antibody 5C6. Thus, the Office Action concludes that applicants have improperly inserted new matter by way of a negative limitation and cites In re Grasselli, 218 USPQ 769 (Fed. Cir. 1983) for support of this allegation.

The Office Action goes on to state that claims 1-8 and 10 are rejected under 35 U.S.C. 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Further stated in the Office Action is that claims 1-8 and 10 are allegedly not supported by the

specification or by the claims as originally filed. The Office Action also states that there is allegedly no support in the specification or claims as originally filed for the recitation “wherein the ligand is not an antibody having the myelomonocytic recruitment inhibiting activity of monoclonal antibody 5C6.” Further stated in the Office Action is that there is allegedly no written description of the claimed invention in the specification or claims as originally filed and thus, the claimed the invention constitutes new matter.

In response, applicants first point out that the purpose of referencing page 22, lines 27-28 of the specification as described above was to show the examiner that the recitation of monoclonal antibody 5C6 is supported at that place in the instant specification by a specific reference (i.e., reference 8). Applicants were not intending, by this citation of page 22, lines 27-28 of the specification, to establish a nexus between “non-opsonizing activity” and not having “myelomonocytic recruitment inhibitory activity” and applicants apologize for any confusion resulting from applicants’ previous response.

Furthermore, applicants note that in support of her allegation that the claims as amended incorporate new matter that is not supported in the specification, the examiner relies on case law which addresses the issue of “incorporation by reference” in a variety of contexts, none of which come close to the facts of the instant application.

Specifically, the examiner cites Advanced Display Systems, citing In re de Seversky, for the proposition that the “host document must identify with detailed particularity what specific material it incorporates and clearly indicate where the material is found in the various documents.”

In Advanced Display Systems, the issue of incorporation by reference is raised solely in the context of whether the determination of what is properly incorporated by reference into a

patent application is a question of law or a question of fact. The materials under evaluation in this regard were documents incorporated by reference into U.S. Patent No. 4,097,127 that disclosed hundreds of different liquid crystal materials that could reflect visible and infrared light. The '127 patent was used as the basis of an argument that the claims of the subject patent of the case, U.S. Patent No. 5,453,863, were invalid as anticipated. The patent infringement defendant argued that the claims of the '863 patent were anticipated by the combination of the '127 patent and three particular liquid crystal materials listed among the hundreds of different liquid crystal materials disclosed in the documents incorporated by reference into the '127 patent.

The court in Advanced Display Systems never addresses the issue of whether the above-described incorporation by reference is proper; the court holds only that the issue of incorporation by reference is a question of law and remands the case for a new trial on the issue of anticipation on the basis that there was prejudicial legal error in the magistrate judge's instruction to the jury that it was their role to determine whether and to what extent material from other documents was incorporated by reference into the '127 patent.

The court in Advanced Display Systems does present a variety of legal interpretations of incorporation by reference to address the specific issue of whether material incorporated by reference can be considered in an anticipation rejection and cites a variety of cases in this regard. For example, the court cites Ultradent Prods., Inc. v. Life-Like Cosmetics, Inc. 44 USPQ2d 1336, 1339-40 (Fed. Cir. 1997) for the proposition that "[m]aterial not explicitly contained in the single, prior art document may still be considered for purposes of anticipation if that material is incorporated by reference into the document." The court also cites General Electric Co. v. Brenner 407 F.2d 1259 and In re Lund 376 F. 2d 982, 989, 153 USPQ 625, 631 (CCPA 1967) for the premise that "incorporation by reference provides a method for integrating material from various documents into a host document – a patent or printed publication in an anticipation determination – by citing such material in a manner that makes clear that the material is

effectively part of the host document as if it were explicitly contained there.” The court goes on to cite In re de Seversky, as noted above by the examiner, in support of the following interpretation: “To incorporate material by reference, the host document must identify with detailed particularity what specific material it incorporates and where that material is found in the various documents.”

Thus, it is apparent that the court in Advanced Display Systems 1) addressed the issue of incorporation by reference only in the context of whether such incorporated material can be considered in an anticipation reference and thus provided no holding on whether and to what extent a particular effort to incorporate material by reference fails or succeeds, and 2) clearly provided among the variety of interpretations of the case law set forth, more than one interpretation by which the material to be incorporated by reference in the instant application would be properly so incorporated (e.g., General Electric and Lund). Thus it is improper for the examiner to rely on a single line of dictum in Advanced Display Systems, without consideration of that line in the context of the entire case, as the basis for an allegedly governing legal interpretation which leads the examiner to the conclusion that applicants’ claims are to be rejected for lack of support in the instant specification because applicants have allegedly failed to properly incorporate by reference the subject matter of the pending claims.

Furthermore, applicants point out that the court in Advanced Display Systems relies upon the following summary of the holding in In re de Seversky in establishing its own interpretation: “...incorporation by reference requires a statement ‘clearly identifying the subject matter which is incorporated and where it is to be found.’” It is applicants’ belief that this summary has been taken out of context by the court in Advanced Display Systems and provide below a detailed examination of the facts in In re de Seversky to demonstrate how this case should have been interpreted.

The issue in In re de Seversky was whether an applicant was entitled to incorporate by reference the subject matter of a grandparent application on the basis that the applicant continuation-in-part application (the application at issue) claimed priority to a parent application which was a continuation-in-part application of the grandparent application. However, 1) the parent application did not recite the subject matter set forth in the grandparent that was critical in a determination of the patentability of the applicant's claims, and 2) the parent application did not contain any language stating that the subject matter of the grandparent application was to be incorporated by reference into the parent application. On these facts, the court held that the applicant was not entitled to incorporate the subject matter of the grandparent application into the application at issue.

Thus, it is apparent from a reading of In re de Seversky that the issue of incorporation by reference was in the context of whether an application contained any statement that subject matter of another patent application was to be incorporated by reference into a specific patent application and the court never addressed or made any comment regarding a situation which would provide for an interpretation that a "...host document must identify with detailed particularity what specific material it incorporates and where that material is found in the various documents." In the context of the facts of this case, the statement in In re de Seversky of "...the incorporation by reference in an application of matter elsewhere written down (not necessarily in a patent application), for economy, amplification, or clarity of exposition, by means of an incorporating statement clearly identifying the subject matter which is incorporated and where it is to be found" can be reasonably interpreted to mean that all the applicant was lacking was a statement in the parent application identifying the grandparent application as the place where the subject matter was to be found and a statement that the subject matter of the grandparent application was to be incorporated by reference, thereby identifying the subject matter to be incorporated. There is nothing in In re de Seversky that would provide for an interpretation that the court in In re de Seversky was stating that the specific subject matter in the grandparent

application upon which the applicant wanted to rely had to be pointed by page and line citation or described with “detailed particularity.” The court’s holding was simple in its interpretation that a referencing statement must be present in an application in order for material from another document to be incorporated. Applicants also note below that in In re Voss, the CCPA points out that the Board of Patent Appeals and Interferences (BPAI) misinterpreted the holding in In re de Seversky.

Applicants’ explanation of the holding in In re de Seversky is consistent with the facts of the present application. Specifically, applicants provide the following statement of incorporation by reference in the instant specification on page 25, lines 24-27: “Throughout this application, various publications are referenced. The disclosures of these publications in their entireties are hereby incorporated by reference into this application in order to more fully describe the state of the art to which this invention pertains.” In addition, applicants reference, and thus incorporate, three publications in the specification that describe art known properties of monoclonal antibody 5C6. These publications are referenced by a number at the place in the specification where the 5C6 antibody is described and each number correlates with a citation of the referenced publication, that is complete with the title of the publication, at the end of the specification where a listing of all cited publications can be found. This format for referencing a publication in a patent application is a standard convention for referencing documents, not only in patent applications but also in manuscripts prepared for publication in peer-reviewed scientific journals and in book chapters. The inclusion of only a number to identify a referenced publication in the text of a document is done for economy of space and is readily recognized to mean that the complete citation for the referenced publication can be found in a reference list somewhere in the document. Thus, in parallel with the facts of In re de Seversky, applicants have properly incorporated these publications into the present application.

The examiner also relies upon Ex parte Raible in support of her contention that the instant specification does not support the subject matter of the pending claims. In Ex parte Raible, the issue under consideration by the court was whether an applicant could rely upon the general incorporation by reference of the subject matter of a patent to support specific claim limitations and whether it would be recognized by one of ordinary skill in the art that the applicant had invented the subject matter as claimed in view of what was to be incorporated. Specifically, the applicant wanted to include a claim limitation directed to “a heat exchange conduit helically disposed” as part of his invention, even though the applicant admitted that his disclosure was “...silent as to the specific nature of the heat exchange surface or elements associated with heat exchange chamber 12 of the depicted apparatus.” The examiner argued that the applicant’s proposed claim limitation constituted new matter. The applicant counter argued that his specification fully supported the claim language by virtue of incorporation by reference of U.S. Patent No. 4,058,369, which apparently provided support only in a drawing for the claim limitation at issue in the rejected claims.

The BPAI distinguished the use of a general incorporation by reference for enablement purposes and for written description purposes. Specifically the BPAI stated that “...the general incorporation by reference in appellant’s specification is sufficient to indicate what is likely to be known by persons of ordinary skill in the art.” The BPAI went on to state that the issue of incorporation by reference must be analyzed in the context of a determination of whether “...the specification describes the invention sufficiently for those of ordinary skill in the art to recognize that the applicant invented the subject matter he now claims.” The BPAI relied significantly on the fact that the applicant’s specification lacked any specific indication of the particular features disclosed in the ‘369 patent and that the specification did not identify any specific portion of the ‘369 patent which the applicant might have intended to rely upon to supplement his disclosure. For this latter concern regarding a lack of any reference to a particular place in the incorporated

reference, the BPAI relies on the holding in In re de Seversky in the same way that the court in Advanced Display Systems did, by interpreting the requirement for "...an incorporating statement clearly identifying the subject matter which is incorporated and where it is to be found" to require more than the court in In re de Seversky intended in order to incorporate material by reference. The BPAI commented that, on the basis of the Raible application, given the '369 patent disclosure, one *might* employ the claim limitations Raible attempts to incorporate, but that this was not sufficient to indicate to one skilled in the art that such claim limitations are described as a particular feature of the applicant's invention. (Emphasis in original) On this basis, the BPAI concluded that the applicant was not entitled to incorporate the necessary subject matter to support his claim limitation.

The BPAI went on to state that for the sake of completeness, it was necessary to distinguish the basis of the opinion in Ex parte Raible from the decision in In re Voss 557 F.2d 812 (CCPA 1977) (copy enclosed). The issue in In re Voss was also incorporation by reference and the holding by the CCPA was that the Voss applicants were entitled to incorporate specific subject matter by reference. The BPAI stated that these cases were distinguishable on these facts and pointed out the following distinctions.

1) In In re Voss, the incorporating statement particularly referred to the aspect of the patent that was being relied upon. That statement is as follows:

A glass-ceramic material is originally formed as a glass which is then phase separated, by a controlled uniform devitrification throughout, to develop a fine crystalline structure within a glassy matrix, the material thus produced having physical properties materially different from the parent glass and more nearly characteristic of a conventional crystalline ceramic material. Reference is made to United States Patent No. 2,920,971, granted to S. D. Stookey, for a general discussion of glass-ceramic materials and their production.

The BPAI compares this statement to what is disclosed in the Raible specification by noting that in the Raible application there is no incorporating statement to any specific portion or aspect of the '369 patent, but that the incorporating statement refers broadly to several patents with no specific indication of the relevance of each to the claimed invention.

2) The BPAI points out that in In re Voss, the disputed claim limitation was found in all of the claims of the incorporated patent and apparently was the central focus of the patent disclosure. With regard to the Raible application, the BPAI notes, the disputed claim language is not found in any claims of the '369 patent and at best may be only incidentally derived after reviewing both the specification and drawings of the '369 patent.

3) The BPAI points out that in In re Voss, the incorporated patent was relied upon merely to clarify the definition of a certain term of art and that in the situation regarding the Raible application, the '369 patent itself does not clearly disclose the claimed combination in language which corresponds to what is recited in the claims.

Applicants believe that the facts of the present application are distinguished from those in Ex parte Raible, wherein the BPAI decided that the efforts to incorporate material into an application by reference were not successful, and more closely parallel the facts in In re Voss, wherein the CCPA decided that the efforts to incorporate material into an application by reference were successful.

As a point of reference regarding the facts of In re Voss, applicants note that the issue in In re Voss was whether the applicant was entitled to rely on subject matter from a parent application in order to include a specific claim limitation and whether it would have been recognized by one of ordinary skill in the art that the applicant invented the subject matter, including this limitation, of applicant's claims. The applicant in In re Voss needed to rely upon

subject matter in U.S. Patent No. 2,920,971, but his application only stated that "reference is made" to this patent "...for a general discussion of glass-ceramic materials and their production." Originally, the BPAI had cited In re de Seversky in its finding that a "mere reference" to the '971 patent in the Voss specification was insufficient to incorporate by reference any portion of the '971 patent into the parent application. Notably, the CCPA reversed the board's decision, stating that the board was misinterpreting that court's decision in In re de Seversky and stated that "[i]t was clear that appellant intended the "discussion of glass-ceramic materials and their production" in Stookey '971 to become part of his patent application."

With this point of reference in mind, applicants set forth herein the facts of the instant case at issue in the context of the three points of distinction set forth above regarding Ex parte Raible and In re Voss. Specifically, regarding item 1, like the application in In re Voss, wherein an incorporating statement was provided which made reference to the material relied upon, the instant application contains a specific statement of incorporation in their entirety of all publications cited in the application and provides three publications (numbered 8, 11 and 13), along with their descriptive titles, in the reference list of the instant application, all of which describe the art known characteristics of monoclonal antibody 5C6, which is shown throughout the instant specification to be part of applicant's invention. (As noted above, it is standard convention to reference publications with a number in the text and a complete citation corresponding to that number in a reference list.) Thus, like the intent of the applicant in In re Voss, it is clear that the instant applicants intend that the art-known characteristics of monoclonal antibody 5C6 be included in the present specification. ✓ 021

As the second point of distinction between the Voss application and the Raible application, the BPAI states that the disputed claim limitation was the central focus of the incorporated patent disclosure in In re Voss but was only incidentally derived after review of both the specification and drawings of the incorporated patent disclosure in Ex parte Raible. The

instant case clearly parallels In re Voss in this regard, because the claim limitation at issue here, i.e., antibodies that have the myelomonocytic recruitment inhibitory activity of monoclonal antibody 5C6, is the central focus of references 8, 11 and 13 cited in the instant application. In fact, monoclonal antibody 5C6 is the only antibody for which data are presented and analyzed in references 8, 11 and 13 and thus the language of the claim limitation at issue here is readily found not only throughout the text of these references, but is implicit in the title of references 8 and 11 as well. -20k

Regarding the third distinguishing feature in a comparison of In re Voss and Ex parte Raible, the BPAI states that the incorporated document in In re Voss was relied upon to clarify the meaning of a term of art set forth in the specification and that in Ex parte Raible, the incorporated document did not clearly disclose the subject matter of the disputed claim limitation in language which corresponded to what was being claimed. Again, in the instant application, like in In re Voss, the incorporated documents merely set forth the art-known characteristics of monoclonal antibody 5C6, which antibody is explicitly set forth in the instant application as part of the invention. an

Thus, the reasoning of In re Voss, rather than of Ex parte Raible, should apply in the present case. Applying the reasoning of In re Voss, the BPAI or a court would likely hold that the subject matter of references 8, 11 and 13 is properly incorporated by reference and that the claim limitation at issue is adequately supported on this basis.

To expand on the relevant points in In re Voss, it is noted that once the CCPA determined that the applicant in In re Voss was entitled to incorporate the subject matter of the '971 patent into his application, the court then analyzed the description requirement issue. The CCPA stated that the PTO has the initial burden of presenting evidence or reasons why one of skill in the art would not recognize in the specification a description of the invention presented in the claims

and further stated that mere lack of literal support is not enough to carry the PTO's initial burden. The CCPA concluded that the "at least 50%" limitation in applicant's claims, which included subject matter found only in the incorporated '971 patent, "...merely quantifies the percentage crystallinity one of ordinary skill at that time would have attributed to the term 'glass-ceramic' material." An equivalent analysis of the instant application would therefore hinge on the question of whether the instant specification describes the invention sufficiently such that one of skill in the art would recognize that the subject matter of the pending claims is within the scope of what the instant applicants describe as their invention. ///

In this regard, applicants submit that, even without relying on subject matter from an incorporated document, it is clear from the instant specification that monoclonal antibody 5C6 is an antibody of the invention and that the myelomonocytic recruitment inhibitory activity of 5C6 is an art recognized characteristic of this antibody as set forth in detail in references 8 and 11, both of which are publicly available. Thus, it would be readily recognized by one of skill in the art, on the basis of the disclosure of applicants' specification, that antibody 5C6 and other antibodies having the characteristics of 5C6 are included within applicants' invention. Support

Furthermore, if the Examiner maintains her position that it is necessary to support the claimed invention by incorporated material, applicants assert that, in view of the case law distinctions and arguments provided herein, applicants are entitled to incorporation by reference of the art known characteristics of antibody 5C6 and that one skilled in the art would readily recognize such antibodies to be part of applicants' invention on this basis as well.

Finally, the Examiner cites In re Grasselli in support of her allegation that applicants have improperly inserted new matter into the claims by way of a negative limitation. With regard to the negative limitation issue, as presented in the previous response, there is precedent in the case law for an inventor to carve out, by negative limitation, less than the whole of what is described

as his invention. Applicants cited In re Johnson and Farnham 558 F. 2d 1008, 194 USPQ 187 (CCPA 1977) to support this position and provided a copy to the Examiner with the previous response. The issue in Johnson was whether the applicants were entitled to carve out a “subgenus,” by way of negative limitation in the claims, of elements that were deemed to be the invention of another. The CCPA held that it was proper to exclude the specific elements because they were adequately disclosed in a priority application and were properly incorporated by reference into the specification at issue. Thus, the CCPA determined that it was clear that the excluded elements were intended to be part of the applicant’s invention and that an inventor is entitled to claim less than the whole of his invention. In the instant application, as applicants have asserted throughout, an antibody having the myelomonocytic recruitment inhibitory activity of 5C6 is clearly part of applicants’ invention and applicants are entitled to claim less than the full scope of their invention, as set forth in In re Johnson and Farnham.

Applicants also wish to point out that In re Grasselli is readily distinguished from In re Johnson and Farnham and from the facts of this case. The applicants in In re Grasselli attempted to introduce, by way of a negative limitation, a claim element that had no support at all in the specification as filed. In contrast, in the instant application, applicants clearly support an antibody having the myelomonocytic recruitment inhibitory activity of 5C6 and disclose 5C6 throughout the specification as a specific and concrete example of such an antibody. Therefore, the facts of In re Grasselli and the BPAI decision based on those facts are not relevant to the case at issue.

Furthermore, applicants cited specific case law in the previous response in support of applicants’ position that the claimed invention is adequately supported and that no new matter is added by the recitation in the claims of an antibody having the myelomonocytic recruitment inhibitory activity of monoclonal antibody 5C6. Applicants note that the only case that the Examiner mentions in the current Office Action is Atmel Corp. v. Information Storage Devices,

Inc. Applicants wish to clarify the facts of Atmel and the facts of the instant application for the Examiner, as these facts appear to be incorrectly set forth on page 3 of the pending Office Action.

In Atmel, the issue under consideration was whether the applicants had provided sufficient disclosure in their specification of a structure that corresponds to a means-plus-function claim limitation. Although the applicant argued that he was entitled to incorporation by reference of subject matter that described the structure at issue, the CAFC upheld the district court's previous holding that, in the context of a means-plus-function claim, the structure at issue must appear in the specification. The CAFC then stated that the real inquiry in this case was whether one skilled in the art would be able to identify the structure at issue from the disclosure in the specification. The court explained that "...the corresponding structure(s) in a means-plus-function limitation must be disclosed in the written description in such a manner that one skilled in the art will know and understand what structure corresponds to the means limitation. Otherwise, one does not know what the claim means."

Although the court in Atmel agreed with the holding by the district court that the article that the applicant sought to have incorporated by reference could not take the place of structure that does not appear in the specification, the CAFC did take note of the fact that the title of the article was part of the specification. The court also considered the testimony of applicant's expert, who stated that "...this title alone was sufficient to indicate to one skilled in the art the precise structure of the means recited in the specification." On this basis, the CAFC determined that, as recognized by one skilled in the art, the specification disclosed sufficient structure to support the means-plus-function claim limitation.

Thus, contrary to the interpretation set forth on page 3 of the current Office Action, the title of the article at issue in Atmel was not "...discussed in the body of the specification in

relationship to the citing of a reference which showed art known features which were taught as being capable of being incorporated into the disclosed invention.” In fact, as explained above, the words of the title of the article at issue in Atmel were relied upon as a physical part of the disclosure of the specification and those words were recognized by one skilled in the art to sufficiently describe the allegedly missing structure which the court said was required in the means-plus-function limitation at issue.

Applicants also note that the Examiner’s summary on page 3 of the Office Action regarding the facts of the instant application is also incorrect. Specifically, it is stated in the Office Action that in the instant case, “...the title is merely cited in a bibliography, and there was nothing in the body of the disclosure to indicate that applicant was directing one to negate embodiments involving an antibody having the myelomonocytic recruitment activity of the monoclonal antibody 5C6.”

Applicants first point out that there is no requirement that the specification direct one to negate an embodiment of an invention in order for applicants to be entitled to set forth a negative limitation in the claims. Applicants have already addressed this issue above, in their discussion of the holding in In re Johnson and Farnham, which provides that an inventor is entitled to claim less than the whole of his invention by carving out, by way of negative limitation, specific elements which are part of the invention. Thus, it is improper for the Examiner to state that the negative limitations of the pending claims constitute new matter on the basis that applicants are required to explicitly state in their specification their intent to negate specific embodiments.

Next, applicants address the Examiner’s comment that the titles at issue herein are merely cited in a bibliography. As applicants have explained above, the numbering of a reference in the body of text and the subsequent description of the reference corresponding to a given number in a bibliography clearly means that it is applicants’ intent that the subject matter of the cited

reference is to be read in the context of the text at the place in the specification where the number appears and subject matter is to be incorporated at that site. The use of the number is merely for economy of space and to imply that a reference to an article would be more relevant if the title of the article is placed within the text instead of the number is improper and illogical.

Applicants also wish to address the facts of the present application in the context of the CAFC's holding in Atmel, wherein the words of the title of the article at issue were considered to be part of the disclosure of the specification and those words were recognized by one skilled in the art to sufficiently support the language of the claims. In applying the same approach to the case at hand, it is applicants' position that the following titles are to be considered a physical part of the disclosure of applicants' specification and that these titles would be recognized by one skilled in the art to support an antibody having the myelomonocytic recruitment inhibitory activity of monoclonal antibody 5C6:

8. Rosen, H. 1990. Role of CR3 in induced myelomonocytic recruitment: Insights from *in vivo* monoclonal antibody studies in the mouse. *J. Leuk. Biol.* 48: 465-469.

11. Rosen, H., G. Milon, and S. Gordon. 1989. Antibody to the murine type 3 complement receptor inhibits T lymphocyte-dependent recruitment of myelomonocytic cells *in vivo*. *J. Exp. Med.* 169:535-549.

13. Rosen, H., S. Gordon, and R. J. North. 1989. Exacerbation of murine listeriosis by a monoclonal antibody specific for the type 3 complement receptor of myelomonocytic cells. *J. Exp. Med.* 170:27-38.

In particular, it would be readily apparent to one skilled in the art from a reading of the title of reference 8 that monoclonal antibodies to CR3 play a role in induced myelomonocytic

recruitment. Furthermore, it would be clear to such an artisan, according to the title of reference 11 that an antibody to CR3 inhibits T lymphocyte-dependent recruitment of myelomonocytic cells *in vivo*. Additionally, it would be recognized that CR3 antibodies exacerbate murine listeriosis. On this basis alone, one skilled in the art would be able to recognize that the applicants of the instant invention describe as part of their invention an antibody to CR3 which has myelomonocytic recruitment activity and provide 5C6 as an example of such an embodiment. The art known fact that antibody 5C6 inhibits myelomonocytic recruitment activity would allow one skilled in the art to readily recognize that antibodies to CR3 having myelomonocytic recruitment inhibitory activity are included within the present invention.

50 is
11
Oct 2

To take the analysis of what one skilled in the art would recognize one step further, it must be considered that each of these three references was publicly available at the time this invention was made. Therefore, one skilled in the art would need only read a few paragraphs of any of these references to conclude that the antibody described in the title is the 5C6 monoclonal antibody, which is explicitly disclosed in the instant specification. Thus, for example, one skilled in the art would logically read into the title of references 8, 11 and 13 the term "monoclonal antibody 5C6" wherever the term "antibody" is recited.

For the reasons set forth above, applicants believe that the pending claims do not constitute new matter and that this rejection should be withdrawn. Applicants respectfully request withdrawal of this rejection and allowance of the pending claims to issue.

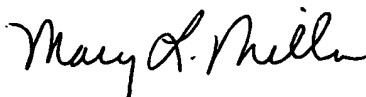
Pursuant to the above remarks, reconsideration and allowance of the pending application is believed to be warranted. The Examiner is invited and encouraged to directly contact the undersigned if such contact may enhance the efficient prosecution of the application to issue.

ATTORNEY DOCKET NO. 14014.0312
Serial No. 09/196,867

No fees are believed due. However, the Commissioner is hereby authorized to charge any fees that may be required, or credit any overpayment to Deposit Account No. 14-0629.

Respectfully submitted,

NEEDLE & ROSENBERG, P.C.

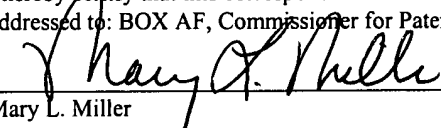


Mary L. Miller
Registration No. 39,303

NEEDLE & ROSENBERG, P.C.
Suite 1200, The Candler Building
127 Peachtree Street, N.E.
Atlanta, Georgia 30303-1811
404/688-0770

Certificate of Mailing

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: BOX AF, Commissioner for Patents, Washington, D.C. 20231, on the date shown below.



Mary L. Miller

Date